REMARKS

This Amendment is in response to the Office Action mailed October 6, 2008.

A petition for a one (1) month extension of time along with the petition fee accompanies this amendment.

As of the mailing of the current Action, claims 23-25, 27-29, 31-45, 47, 51, 68 - 71 are pending. Applicant respectfully directs attention to the Request of Continuation (RCE) filed August 20, 2008. New claims 70 and 71 were presented for examination in the listing of the claims. The current Office Action does not acknowledge pendency of claims 70 and 71. Appropriate correction is requested.

Reconsideration of the subject application is respectfully requested.

I. Terminal Disclaimer

The current Office Action, on pages 5-6, has set forth a provisional rejection based on nonstatutory obviousness type double patenting over copending application 10/910,787. Applicant submits herewith a terminal disclaimer along with the disclaimer fee to obviate this rejection. Applicant respectfully requests reconsideration and withdrawal of this rejection.

II. REJECTIONS UNDER 35 USC 103(a)

Claims 23-25, 27-29, 31-45, 47, 51, 68, and 69 have been rejected under 35 USC 103(a) as being unpatentable over Skinner (US Pat No. 6,210,710), in view of Miller (US Pat Application Publication No 2005/0008690) further in view of Cristoferi et al. (US Pat. No. 5,252,339).

Applicant notes that rejections over prior art were made in the current Office Action. As such, in view of MPEP 707.07 that requires the Action to be complete as to all matters, Applicant's response presented herein is based on the cited references. Applicant understands the MPEP requirement of completeness that the currently pending claims being allowable upon a showing that the claimed invention is patentable over these cited references.

The subject invention, as now claimed, requires, inter alia:

> glucosamine or chondroitin to be released at a controlled rate and a formulation coated onto said inert spheres comprising the components (1) a saccharide, (2) a lubricant, (3) a solution having a stabilizing agent, Glucosamine or chondroitin is present in an amount of about 60% to about 95% by weight; (2) said saccharide is present in an amount of about 1.5% to about 15% by weight; (3) said lubricant is present in an amount of about 0.3% to about 3% by weight; (4) said stabilizing agent is present in an amount of about 20% to about 80% (currently amended claim 23).

The present invention specifically claims a formulation coated onto inert spheres.

However, the present rejection set forth in the Office Action mailed October 6, 2008 does not address the limitations of the pending claims as amended in the RCE filed in the subject application. The RCE specifically amended claims 23, 24, 25, 27-29, and 48.

The combined disclosure of the cited references, for reasons set forth below, are deficient for failing to teach or suggest the formulation claimed in the present invention.

Skinner, as cited on page 4 of the current Office Action, discloses a composition that is "beneficial because it provides

flexibility in release profiles that are stable and economical for compressed tablets (Skinner, col. 1, lines 48-56, emphasis added). The Skinner reference is directed to tablet formulations. It is well-known to a person having ordinary skill in the art of formulations that there are a multitude of different variables that require consideration during formulation development. Formulation considerations are quite different between compressed tablets and pellets. The Office Action states that "one would have been motivated to make such a composition because it provides flexibility in release profiles that are stable and economical for compressed tablets" (Office Action, page 5, emphasis added). The present invention is not a compressed tablet, it is layered pellets.

Additionally, in order to use a reference as prior art, the MPEP 2141.02 and applicable case law provide "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983).

The Office Action directs attention, on page 6-item 1, to Skinner, col. 5, line 14 as support for pellet formulations.

Applicant respectfully points to col. 5, lines 23-24 that states "All work discussed in this patent was done as a single layer compressed tablets." The disclosure in this section of Skinner of "layers" refer to layers on a compressed tablet. Pellet dosage forms were certainly known at the time the Skinner patent was invented. Pellet forms are not discussed in Skinner precisely because the formulation considerations are different between compressed tablets and pellets.

When viewing Skinner as a whole, there is no sufficient teaching for the Glucosamine or chondroitin pellet formulations claimed in the subject application.

The Office Action further combines the disclosure of Skinner with Miller to cure the deficiencies admitted to on page 4 of the current Office Action. However, the disclosure of Miller fails to cure the deficiency of Skinner. Miller is cited merely to teach some of the specific limitations of pending dependent claims (see Office Action, page 5). Miller does not have any teaching or suggestion for a formulation to be layered on inert spheres, as currently claimed. The disclosure of Miller is for multi-phase, multi-compartment capsular delivery. The Office Action directs attention to Miller inner alia:

> In one presently preferred embodiment of the present invention, therapeutically effective amounts of glucosamine, chondroitin, and vitamin E (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein at least two of the active ingredients have physical states (e.g., solid, liquid, gas or dispersion) that differ. Consistent with the foregoing, multi-compartment, multi-phase capsules and encapsulation technology are herein contemplated to produce a delivery vehicle for delivering anti-arthritic and anti-oxidant compounds to the body in a single dosage (Miller, paragraph [0306].

Miller only discloses delivery by placement in a capsular compartment.

This teaches away from the subject invention that controls delivery by way of a functional coating on a plurality of pellets.

Miller further has mere lists of possible materials they may be incorporated into a dosage form but contains no teaching on how to achieve formulations of the present invention. The Office Action cites disclosure of shellac. All Miller discloses is:

> Still further by way of example and not by limitation, the present invention can be utilized with the following exipients: Magnesium Stearate Povidone Lactose

> Pregelatinized Starch Microcrystalline Hydroxy Propyl Cellulose Methylcellulose Starch (corn) OPA products (coatings Silicon Dioxide & inks) Titanium Dioxide Croscarmellose Stearic Acid Hydroxy Propyl Cellulose Sodium Starch Ethylcellulose Glycolate Calcium Phosphate (dibasic) Gelatin Crospovidone Talc Shellac (and Glaze) Sucrose Calcium Stearate (Miller, paragraph [1548]).

This is only a long list of ingredients. There is no disclosure at all relating to use of shellac as a controlled release pellet coating. There is no teaching of how to formulate and apply a pellet coating. There is no teaching of how to achieve the claimed release profile.

This is the same as if a reference listed "flour." It can be used for bread, for cake, or for modeling clay! There must be some teaching or suggestion found in the prior art reference as to use and formulation of this material. Miller only provides a listing and has no such teaching or suggestion.

Again, Applicant reminds the Office that, as stated above, the prior art must be viewed as a whole. Thus, Skinner in view of Miller, fails to teach or suggest the subject invention as now claimed.

The Office Action, on page 5, cites the Cristofori reference to teach diethyl phthalate.

The combined disclosures of Skinner, Miller, and Cristofori, as a group, have all the ingredients listed. But, there is nothing in the combined disclosures that teaches or suggests how to formulate the pellets of the present invention and how to formulate the pellets that exhibit the claimed release profile.

Applicant reminds the Office of the long-standing principle that the chemical arts are highly unpredictable and require a higher standard for obviousness determinations.

> Although there is a vast amount of knowledge about general relationships in the chemical arts, chemistry is still largely empirical, and there is often great difficulty in predicting precisely how a given compound will behave. In re Dillon 919 F.2d 688, 710 (Fed Cir.,1990).

Recently, the USPTO published its "Examination Guidelines for Determining Obviousness Under 35 USC 103 In View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*" See, FR Vol. 72, No. 195, pp. 57527-57335, Oct. 10, 2007 (hereinafter, the "Guideline") The Guideline states that, in

considering obviousness of an invention, even for a combination of known elements, the "operative question is thus 'whether the improvement is more than the predictable use of prior art elements according to their established functions (See "Guideline" at page 57527, col. I, quoting KSR, 550 US at 82 USPQ 2nd at 1391..)

As detailed herein, even assuming the subject invention has, in part, the elements of the prior art, the subject invention is "more than the predictable use of prior art elements according to their established functions" ("Guideline" at page 57527). Chemistry is very unpredictable, and the present invention requiring layered pellets and specific release profile is the result of the inventor's skill in the art to arrive at a novel formulation and desired release profile which is significantly more than the "predictable use" discussed in *KSR*. Specifically, the claimed invention results in formulation having the desired, unexpected, and advantageous result that provides for pellets of Glucosamine or chondroitin with a specific in vivo release profile. This pellet formulation is not taught or suggested in the combined disclosure of Skinner, Miller, and Critofori.

Thus, a determination of non-obviousness is believed to be

required in answer to the "operative question" identified in the PTO's own Guideline.

As stated above, Skinner teaches beneficial tablet formulations and has no disclosure for a composition with a formulation layered onto inert spheres as presently claimed. Combination of the teaching of Skinner with the teaching of Miller does not render the subject invention obvious because, as stated above, chemistry is recognized as being unpredictable and Miller only provides lists of possible ingredients and has no teaching or suggestion for the claimed formulation layered on inert spheres. Cristofori is also a reference relating to tablet formulations and, combined with the disclosure of Skinner and Miller, does not cure the deficiency of failing to teach or suggest the pellet formulation of the present invention. The combined disclosure of the cited references, as discussed herein, are deficient in their teaching and cannot be used to properly support an obviousness rejection.

In view of the failure of the combined disclosure of the cited references to teach, suggest, or provide any type of motivation to modify, in order to achieve the desired and claimed pellet formulation, Applicant asserts a rejection under 35 USC 103(a)

cannot be properly applied. Applicant respectfully requests reconsideration withdrawal of this rejection.

Furthermore, because there are no rejections set forth in the Office Action to claims 70-71, Applicant proceeds with the understanding that claims 70-71 are allowable.

Based on the Amendments presented herein, Applicant respectfully asserts the application is patentable over the prior art and is now in condition for allowance. If the Examiner believes there are any additional issues that have not been resolved, the Examiner is invited to call the undersigned representative who is attorney of record in this case.

Applicant asserts, no new matter is added by these amendments.

The Commissioner is hereby authorized to charge our Deposit Account No. 19-0734 should any additional fee(s) be required in the filing of this paper to expedite the examination of this application.

Respectfully submitted,

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